

REMARKS

This Amendment is submitted in response to the Non-Final Office Action mailed on November 29, 2007. Please charge Deposit Account No. 02-1818 and charge any other fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-626 on the account statement.

Claims 1-12 are pending in the application. In the Office Action, Claim 1-12 are rejected under 35 U.S.C. §103. In response, Applicants have amended Claims 7, 10 and 11. The amendments do not add new matter and find support in the specification (Preliminary Amendment) at page 5, lines 10-16 and page 6, lines 3-5. Applicants have also added new Claim 13. Claim 13 does not add new matter and finds support in the specification at page 16, lines 24-26. In view of the amendments and for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1, 2, and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/31130 to Mazer et al. ("*Mazer*") in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, "Lactic acid and its ammonium, calcium, potassium, and sodium salts", World Health Organization Technical Report Series, 1974, No. 539) ("*WHO*"). Independent Claim 1 recites, in part, a nutritional formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+) lactic acid, the formula is directly acidified. Amended independent Claims 7, 10 and 11 recite, in part, a method of preparing nutritional formulas comprising the step of directly acidifying the nutritional formula by using L(+) lactic acid. Even if the cited references are combinable, which Applicants submit they are not, the cited references still fail to disclose or suggest every element of the rejected claims.

Mazer fails to disclose or suggest a formula directly acidified with L(+) lactic acid as required by Claim 1 or directly acidifying a nutritional formula with L(+) lactic acid as required by method Claims 7, 10 and 11. Though the Office Action asserts that *Mazer* teaches the use of purified lactic acid as an acidulant in beverages and beverage concentrates, this "purified lactic acid" is actually a fermented lactic acid. See, *Mazer*, page 34. By contrast, the present claims

teach direct acidification such that a fermentation process does not produce the L(+) lactic acid. See, specification, page 6, lines 15-18.

By avoiding the fermentation step, the optional drying process will be much more efficient, due to the fact that a fermentable solution with low dry-matter content may be avoided. The whole process may be conducted at higher dry matter, thus superseding an evaporation-step or drying of a solution at a high water content. See, specification, page 9, lines 1-4. Moreover, by directly acidifying using L(+) lactic acid, one can produce nutritional formulas having bacteriostatic activity while being nutritionally safe for infants. See, specification, page 5, lines 10-12.

Mazer also fails to disclose or suggest the any use of L(+) lactic acid in its beverage. The Office Action admits the same. See, Office Action, page 3, No. 8. Applicants respectfully submit that *WHO* fails to remedy the deficiencies of *Mazer*.

WHO also fails to disclose or suggest a formula directly acidified with L(+) lactic acid as required by Claim 1 or directly acidifying a nutritional formula with L(+) lactic acid as required by method Claims 7, 10 and 11. Instead, the Office Action only relies on *WHO* arguably to disclose L(+) lactic acid rather than a direct acidification step. See, Office Action, page 3, No. 9. Moreover, *WHO* teaches acidifying with general DL-lactic acid and not direct acidification with specific L(+) lactic acid. See, *WHO*, page 5.

Further, *WHO* fails to disclose or suggest use of L(+) lactic acid. The Office Action asserts, however, that because DL-lactic acid and D(-) lactic acid should not be used in infant foods, this only leaves L(+) lactic acid for use in infant foods. See, Office Action, page 3, No. 9. Applicants respectfully submit that this assertion misinterprets DL-lactic acid. DL-lactic acid is a racemic mixture of L(+) and D(-) lactic acid forms. As a result, because the experiments in *WHO* show that infants had difficulty utilizing DL and D(-) lactic acids, infants inherently had difficulty utilizing the racemic mixture of L(+) and D(-) lactic acid forms. Therefore, no part of *WHO* teaches that infants can positively utilize L(+) lactic acid. Instead, based on the negative results of the racemic DL lactic acid, *WHO* actually teaches away from using L(+) lactic acid in nutritional compositions.

Accordingly, *WHO* fails to remedy the deficiencies in *Mazer* because (a) *WHO* fails to disclose or suggest a formula or method for direct acidification using L(+) lactic acid and (b)

WHO fails to disclose or suggest the use of L(+) lactic acid in nutritional formulas and actually teaches away from using L(+) lactic acid in nutritional formulas.

Therefore, the combination of *Mazer* in view of *WHO* fails to disclose or suggest every element of the present claims.

In the Office Action, Claims 1, 3-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Schwartz, A.B. 1926, "The Use of Lactic Acid Milk in Infant Feeding", The American Journal of Nursing, Vol. 26, No. 12, pp. 927-932) ("*Schwartz*") in view of *WHO* with additional evidence provided by Wong et al. (1999, Fundamentals of Dairy Chemistry, 3rd Edition, pp.1, 82-83, Springer – Verlag) ("*Wong*"). Even if the cited references are combinable, which Applicants submit they are not, the cited references still fail to disclose or suggest every element of the rejected claims.

Schwartz fails to disclose or suggest a formula directly acidified with L(+) lactic acid as required, in part, by Claim 1. The Office Action admits the same. See, Office Action, page 4, No. 15. As stated previously, *WHO* fails to remedy this deficiency with regard to L(+) lactic acid because (a) *WHO* fails to disclose or suggest a formula for direct acidification using L(+) lactic acid and (b) *WHO* fails to disclose or suggest the use of L(+) lactic acid in nutritional formulas and actually teaches away from using L(+) lactic acid in nutritional formulas. Moreover, *Wong* also fails to remedy this deficiency as the Office Action only relies on *Wong* arguably to disclose proteins comprising whey protein and casein. See, Office Action, page 4, No. 14.

Therefore, the combination of *Schwartz* in view of *WHO* and *Wong* fails to disclose or suggest every element of the present claims.

In the Office Action, Claims 1 3-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,212,893 to Takahata ("*Takahata*") in view of *WHO* with additional evidence provided by *Wong*. Even if the cited references are combinable, which Applicants submit they are not, the cited references still fail to disclose or suggest every element of the rejected claims.

Takahata fails to disclose or suggest a formula directly acidified with L(+) lactic acid as required by Claim 1. The Office Action admits the same. See, Office Action, page 5, No. 22. As stated previously, *WHO* fails to remedy this deficiency with regard to L(+) lactic acid because

(a) *WHO* fails to disclose or suggest a formula for direct acidification using L(+) lactic acid and
(b) *WHO* fails to disclose or suggest the use of L(+) lactic acid in nutritional formulas and actually teaches away from using L(+) lactic acid in nutritional formulas. Moreover, *Wong* also fails to remedy this deficiency as the Office Action only relies on *Wong* arguably to disclose proteins comprising whey protein and casein. See, Office Action, page 5, No. 21.

Therefore, the combination of *Takahata* in view of *WHO* and *Wong* fails to disclose or suggest every element of the present claims.

Accordingly, Applicants respectfully request that the obviousness rejections of Claims 1-12 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

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